

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
75-051

BIOEQUIVALENCE

OFFICE OF GENERIC DRUGS
DIVISION OF BIOEQUIVALENCE

Metoclopramide Oral Solution		UDL Laboratories	
5 mg/5 mL		Largo, FL	
ANDA #75051		Submission Date:	
Reviewer: Moo Park		December 30, 1996	
REF PRODUCT	A. H. Robins' Reglan [®] Syrup, 5 mg/5 mL		
BE STUDY DESIGN	n/a		
STUDY SITE	n/a		
STUDY SUMMARY	n/a		
BIOASSAY VALIDATION	n/a		
DISSOLUTION	n/a		
WAIVER	<ol style="list-style-type: none"> 1. Metoclopramide Oral Solution is an AA rated oral solution. 2. The test product contains metoclopramide in the same concentration as the reference product. The test product contains the same inactive ingredients qualitatively as the reference product except flavors and propylparaben. 3. Waiver is granted for UDL's Metoclopramide Oral Solution, 5 mg/5 mL strength. 		

<p>INITIAL: <u><i>Moo Park</i></u></p> <p>REVIEWER: Moo Park, Ph.D.</p> <p>BRANCH: III</p> <p>INITIAL: <u><i>Ramakant M. Mhatre</i></u></p> <p>TEAM LEADER: Ramakant M. Mhatre, Ph.D.</p> <p>BRANCH: III</p> <p>INITIAL: <u><i>Nicholas Fleischer</i></u></p> <p>DIRECTOR: Nicholas Fleischer, Ph.D.</p> <p>DIVISION OF BIOEQUIVALENCE</p> <p>INITIAL: _____</p> <p>DIRECTOR</p> <p>OFFICE OF GENERIC DRUGS</p>	<p>DATE: <u><i>6/16/97</i></u></p> <p>DATE: <u><i>6/16/97</i></u></p> <p><i>The difference in amount of citric acid and glycerin should have no impact on BA/BE.</i></p> <p>DATE: <u><i>8/13/97</i></u></p> <p><i>Waiver appropriate under 320.24(b)(6)</i></p> <p>DATE: _____</p>
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Metoclopramide Oral Solution	UDL Laboratories
5 mg/5 mL	Largo, FL
ANDA #75051	Submission Date:
Reviewer: Moo Park	December 30, 1996
Filename: 75051w.d96	

Review of a Waiver Request

I. Objective

Review of UDL's waiver request for its Metoclopramide Oral Solution, 5 mg/5 mL strength. Reference product is A. H. Robins' Reglan^R Syrup, 5 mg/5 mL.

II. Comment

1. Metoclopramide Oral Solution is an AA rated oral solution.
2. The test product contains metoclopramide in the same concentration as the reference product. The test product contains the same inactive ingredients qualitatively as the reference product except flavors and propylparaben. These differences are not likely to affect absorption of the active drug ingredient. The test formulation is shown in Table 1.

Table 1. Test Formulation

Ingredient	Amount mg/5 mL
Metoclopramide Hydrochloride	(=5.0 as base)
Methylparaben	
Citric acid	
Sorbitol Solution	
Glycerin	
Artificial flavor	
FD&C Yellow	
Purified Water USP	

3. Waiver is granted for UDL's Metoclopramide Oral Solution, 5 mg/5 mL strength.

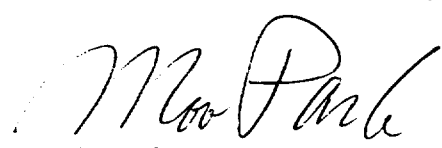
III. Deficiency

None.

IV. Recommendation

The Division of Bioequivalence agrees that the information submitted by UDL demonstrates that Metoclopramide Oral Solution, 5 mg/5 mL strength, falls under 21 CFR Section 320.22 (b) of the Bioavailability/ Bioequivalence Regulations. The waiver of in vivo bioequivalence study for UDL's Metoclopramide Oral Solution, 5 mg/5 mL strength, is granted. From the bioequivalence point of view, the Division of Bioequivalence deems the test Metoclopramide Oral Solution, 5 mg/5 mL strength to be bioequivalent to A. H. Robins' Reglan^R Syrup, 5 mg/5 mL.

The firm should be informed of the recommendation.


Moo Park, Ph.D.
Chemist, Review Branch III
Division of Bioequivalence

RD INITIALED RMHATRE

FT INITIALED RMHATRE

Ramakant M. Mhatre, Ph.D.

Team Leader, Review Branch III

Division of Bioequivalence

Ramakant M. Mhatre 5/13/97

Concur:

fr

Nicholas Fleischer, Ph.D.

Director

Division of Bioequivalence

N. Baluach

Date:

5/16/97

cc:

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